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PARLIAMENT OF INDIA
RAJYA SABHA

58

DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE

FIFTY-EIGHTH REPORT

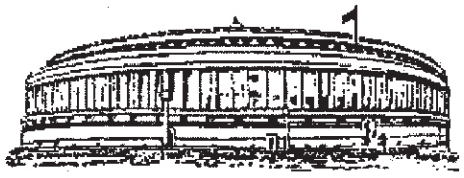
ON

ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS/OBSERVATIONS CONTAINED IN THE FORTY FIFTH REPORT ON ISSUES RELATING TO AVAILABILITY OF GENERIC, GENERIC-BRANDED AND BRANDED MEDICINES, THEIR FORMULATION AND THERAPEUTIC EFFICACY AND EFFECTIVENESS

(MINISTRY OF HEALTH AND FAMILY WELFARE)

(PRESENTED TO THE RAJYA SABHA ON 8TH MAY, 2012)
(LAID ON THE TABLE OF LOK SABHA ON 8TH MAY, 2012)

RAJYA SABHA SECRETARIAT
NEW DELHI
MAY, 2012/VAISHAKHA, 1934 (SAKA)



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MAY, 2012/VAISHAKHA, 1934 (SAKA)

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COMPOSITION OF THE COMMITTEE
(2011-2012)

RAJYA SABHA

1. Shri Brajesh Pathak — *Chairman*
[#]2. Shri Janardhan Dwivedi
*3. Shrimati Viplove Thakur
4. Dr. Vijaylaxmi Sadho
5. Shri Balbir Punj
6. Dr. Prabhakar Kore
7. Shrimati Vasanthi Stanley
[@]8. Shri Rasheed Masood
9. Shrimati B. Jayashree
10. Shri Derek O'Brien

LOK SABHA

11. Shri Ashok Argal
12. Shrimati Harsimrat Kaur Badal
13. Shri Vijay Bahuguna
14. Shrimati Raj Kumari Chauhan
15. Shrimati Bhavana Gawali
16. Dr. Sucharu Ranjan Haldar
17. Dr. Monazir Hassan
18. Dr. Sanjay Jaiswal
19. Shri S. R. Jeyadurai
20. Shri P. Lingam
21. Shri Datta Meghe
22. Dr. Jyoti Mirdha
23. Dr. Chinta Mohan
24. Shri Sidhant Mohapatra
25. Shrimati Jayshreeben Kanubhai Patel
26. Shri M. K Raghavan
27. Shri J. M. Aaron Rashid
28. Dr. Arvind Kumar Sharma
29. Shri Radhe Mohan Singh
30. Shri Ratan Singh
31. Dr. Kirit Premjibhai Solanki

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*
Shri R.B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Dinesh Singh, *Deputy Director*

Ceased to be a Member *w.e.f.* 27th January, 2012 and re-nominated to the Committee on 2nd February, 2012.
* Ceased to be a Member *w.e.f.* 2nd April, 2012.
@ Ceased to be a Member *w.e.f.* 9th March, 2012.

SUB-COMMITTEE III ON DRAFT REPORTS – HEALTH AND FAMILY WELFARE

1. Dr. Jyoti Mirdha — *Convenor*

RAJYA SABHA

2. Shri Balbir Punj

LOK SABHA

3. Dr. Sanjay Jaiswal

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*
Shri R.B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Dinesh Singh, *Deputy Director*

PREFACE

I, the Chairman of the Department-related Parliamentary Standing Committee on Health and Family Welfare, having been authorized by the Committee to present the Report on its behalf, hereby present this Fifty-Eighth Report on the action taken by the Department of Health and Family Welfare on the recommendations/observations contained in the 45th Report of the Committee on "Issues Relating to Availability of Generic, Generic-Branded and Branded Medicines, their Formulation and Therapeutic Efficacy and Effectiveness".

2. The Committee had presented its 45th Report to both Houses of Parliament on the 4th August, 2010. The Ministry of Health and Family Welfare furnished an Interim Action Note (ATN) on the 5th January, 2011 and Final Action Taken Note on the 23rd May, 2011 on the recommendations/observations as contained in the 45th Report of the Committee. Subsequent to the receipt of the Interim Action Taken Note, the Committee took oral evidence of the representatives of Ministry of Health and Family Welfare and the Secretary, Department of Pharmaceuticals on the 18th February, 2011 to holistically examine the issues arising out of the Interim Action Taken Note. Upon receipt of the final Action Taken Note, the Committee again took oral evidence of the Secretary, Ministry of Health and Family Welfare and Secretary, Department of Pharmaceuticals on the 3rd June, 2011 to evaluate the substantiveness of the action as indicated in the final ATN.

3. The Committee made use of the following documents/information in finalising its Report:–

(i) Interim and Final Action Taken Notes furnished by the Ministry of Health and Family Welfare on the recommendations as contained in the 45th Report of the Committee;

(ii) Oral evidences tendered by the representatives of Ministries of Health and Family Welfare and Chemicals and Fertilizers, Department of Pharmaceuticals before the Committee; and

(iii) Replies received from the Ministry of Health and Family Welfare to the Questionnaire.

4. The Sub-Committee III on Draft Reports considered and adopted the Report at its meeting held on 11th April, 2012.

5. The Committee at its meeting held on 4th May, 2012, considered and adopted the Draft Report.

6. For facility of reference and convenience, observations and recommendations of the Committee have been printed in bold letters in the body of the Report.

BRAJESH PATHAK
Chairman,
Department-related Parliamentary
Standing Committee on Health and Family Welfare.

NEW DELHI;
4th May, 2012
Vaishakha 14, 1934 *(Saka)*

REPORT

Introduction

1. The Committee examined issues of making quality-assured medicines available to the people at affordable price and reducing out-of-pocket expenses by making available low cost quality generic medicines and presented its 45th Report on "Issues Relating to Availability of Generic, Generic-branded and Branded Medicines, Their Formulation and Therapeutic Efficacy and Effectiveness" which was presented to the Parliament on the 4th August, 2010. The Department of Health and Family Welfare initially furnished the Interim Action Taken Notes. The Committee, then, directed that a comprehensive Action Taken Note be furnished incorporating pointed information and the progress made towards addressing the issues highlighted in its 45th Report. Thereafter, the Department of Health and Family Welfare *vide* its communication dated the 23rd May, 2011 furnished the final Action Taken Note.

2. Action Taken Notes have been categorized as follows:

CHAPTER I	Recommendations/Observations in respect of which replies of the Government have been accepted by the Committee-Para Nos. 28, 29 Total-2
CHAPTER II	Recommendations/Observations which the Committee does not desire to pursue in view of the Government's replies—NIL
CHAPTER III	Recommendations/Observations in respect of which replies of the Government have not been accepted by the Committee Para Nos. 18, 19, 21, 22, 26, 27, 31, 32, 33, 34, 35, 36, 37 **Total-13** (Chapter III)
CHAPTER IV	Recommendations/Observations in respect of which final replies of the Government are still awaited—NIL

CHAPTER-I

RECOMMENDATIONS/OBSERVATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT HAVE BEEN ACCEPTED BY THE COMMITTEE

Recommendations/Observations

1. In paras 28 and 29 of its 45th Report, the Committee had made recommendations on inclusion of more essential and life-saving drugs under price regulation and making the Drug Price Control Order (DPCO) more rational. The recommendations made in these paras are quoted below:–

2. "The Committee is shocked to note that despite there being irrefutable evidence of a strong link between high prices of medicines and poverty as also despite the fact that the Eleventh Five Year Plan's one of the avowed objectives is to include all essential drugs under a system of price regulation, the number of drugs under price control still remains at a pathetic 74. The Committee is not aware of the reasons behind reducing the number of drugs under price control and, therefore, would like to be enlightened about the reasons behind restricting the controlled drugs to a mere 74. Prescription of irrational and useless drugs by many of the doctors with ulterior motives is rampant. The Committee is, therefore, convinced that there is no other alternative but to include more essential and life saving drugs under price regulation". (Para 28)

3. "The Committee simultaneously recommends that the Department of Health and Family Welfare take up the matter with the Department of Pharmaceuticals at the highest level with a view to revisiting the issue of inclusion of drugs in the DPCO and making it more rational and patient-friendly. The Committee would like to be kept informed of the action taken in this regard". (Para 29)

Action Taken by the Government

A. Written Submissions

4. In its consolidated reply to the issues highlighted in paras 28 and 29, the Ministry of Health and Family Welfare furnished the following facts in the ATN:–

5. "The Expert Committee set up by the Ministry of Health & Family Welfare finalized its report and submitted a revised National List of Essential Medicines (NLEM) 2011 which contains 348 single ingredients/generic drugs for primary, secondary and tertiary categories. Necessary action has been initiated to get the National List of Essential Medicines (NLEM) 2011 approved by the competent authority. After its approval, the list will be sent to the Department of Pharmaceuticals with a request to take the list into account while revisiting the issue of inclusion of drugs in the DPCO".

Submissions made during the course of Oral Evidence

6. The Secretary (Pharmaceuticals) during his oral evidence before the Committee on 18th February, 2011 made the following submissions:–

- ➢ There is a list of the drugs, the pricing of which National Pharmaceutical Pricing Authority regulates.

- ➢ The drug list was finalized in 1994.
- ➢ The policy of 1994 was approved by the Government in which the criterion for price control was that wherever there was an element of monopoly, and prices were artificially high on account of lack of competition, those drugs were identified for price control.
- ➢ In 2002, it was decided to alter the formula for assessing monopoly element by increasing the limits.
- ➢ The Department of Pharmaceuticals is working on having a revised policy and examining whether the criteria should be essentiality or it should be some other form of monopolistic control, for which National List of Essential Medicines, which is being finalized, would be one of the inputs.
- ➢ This issue is also part of the mandate of one of the two Working Groups.

7. On being asked whether the Department of Pharmaceuticals was looking into expansion or contraction of drugs under price control, the Secretary (Pharmaceuticals) did not give a categorical reply and instead stated that the entire gamut of issues was being looked into. In reply to another query regarding the time-frame for revision of the list of drugs under price control, he again, did not give a straight answer and only stated that the issue of revising the Pharmaceutical Policy was pending with the Group of Ministers and one of the issues in that policy was to revise the span of price control over drugs. During the course of his subsequent deposition before the Committee on 3rd June 2011, the Secretary (Pharmaceuticals) informed that there were 74 bulk drugs in the Drug Price Control Order 1995, out of which 42 were actively in vogue. He also informed that his Department was waiting for the National List of Essential Medicines 2011 and now that the list had been received, they would be able to finalise the New Pharmaceutical Policy. He also stated that the New Pharmaceutical Policy would be finalized within a period of six months.

CHAPTER-II

RECOMMENDATIONS/OBSERVATIONS WHICH THE COMMITTEE DOES NOT DESIRE TO PURSUE IN VIEW OF THE GOVERNMENT's REPLIES

-NIL-

CHAPTER-III

RECOMMENDATIONS/OBSERVATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT HAVE NOT BEEN ACCEPTED BY THE COMMITTEE

Recommendations/Observations

1. The Committee in para 18 of its 45th Report had cited the following examples:

   (i) Chittorgarh model for making affordable medicines available to patients through Low Cost Drug Shops selling generic medicines by involving Government Co-operative Medical Stores in procurement of generic medicines through open tender.

   (ii) Bihar model of every medical college, district hospital and PHC having a shop and selling generic medicines at less than 50 per cent of the MRP and yet Bihar Government earning 45 per cent revenue on the project; and

   (iii) Tamil Nadu model of finalizing list of the Essential Drugs based on National List of Essential Medicines (NLEM) and purchasing only generics, ensuring adequate funds and human resources for supply of drugs from its warehouses to various points of health care delivery associated with testing of drugs for quality, supplying drugs only in strips and blister packing, etc. which resulted in huge savings on expenditure on drugs and enabled rational use of drugs.

2. The Committee felt that the above examples are worth emulating and recommended emulation of the above models.

Action Taken

3. "The Ministry of Health & Family Welfare has been pursuing the matter for opening of additional Jan Aushadhi Centres with the Department of Pharmaceuticals. That Department has been requested on 30th March, 2011 to first focus on the target of one such Jan Aushadhi Store in each district across States and also to engage private sector, if possible, to supplement the efforts of PSUs to supply generic medicines to Jan Aushadhi Centres at the same prices as are being supplied by PSUs. As per available information, 82 Jan Aushadhi Stores have so far been started. The Ministry of Health & Family Welfare will continue to pursue this matter with the Department of Pharmaceuticals."

4. "The issue of promotion of quality generic drugs in the country was also considered by the Drugs Consultative Committee, a Statutory Committee under the Drugs & Cosmetics Act, in its meeting held on 28.10.2010 and it was suggested that the State Drugs Control Authorities may grant licenses for manufacturing of single drug formulations in generic names only to promote availability of generic drugs at affordable prices in the country. This issue was again discussed by the Drugs Consultative Committee in its next meeting held on 15.2.2011. DCGI has been asked to regularly pursue this matter with the State Drugs Control Authorities."

Recommendations/Observations

5. In paras 19, 21, 32 and 33 of its 45th Report the Committee had recommended for convening of a meeting of the Chief Secretaries of the State Governments for the purpose of

formulating an effective" essential drug supply policy", proactive intervation by the State Governments in procurement of life-saving medicines at affordable prices, limitations in going for a "generic only" policy and procurement of generic drugs in bulk from manufacturers and dispensing them directly to patients through health centres. These paras are quoted below for the facility of ready reference:–

6. "The Committee recommends that the Department of Health and Family Welfare, in coordination with the Department of Pharmaceuticals, should convene a meeting of Chief Secretaries of State Governments for the purpose of formulating an effective' essential drug supply' policy, having the components of (a) generic prescribing, (b) adoption of essential drugs list, (c) standard treatment guidelines, (d) drug procurement by open tender system, (e) distribution of low cost drugs through Government drugs stores and (f) demand generation of generics through public awareness. The Committee desires to be kept apprised of the action taken in this regard." (Para 19)

7. "The Committee was also informed that for making available medicines at affordable prices, a campaign, 'Jan Aushadhi' had been launched by the Department of Pharmaceuticals, to sell quality generic medicines. As of now, 46 Jan Aushadhi Stores have been opened across the country. The Committee, however, feels that in a country of 110 crores plus people, even hundreds of Jan Aushadhi stores are unlikely to make a significant dent. Therefore proactive intervention by State Governments down to District levels is required to help the people to procure life saving medicines at affordable prices." (Para 21)

8. "One of the suggestions put forth before the Committee was to make it mandatory for all doctors to write all prescriptions in generic names only. However, the Committee feels that going for a "generic only" prescription policy had its flip side. Even if the doctor prescribes a drug by generic name, the chemist will be free to dispense any equivalent. Thus the power will shift from doctors to the chemists. The pharma companies would unethically start wooing the chemists instead of doctors. This will be worse than current situation. If the patient does not get any relief, doctor will blame the chemist. Moreover while the doctor has some interest in the continued patronage from the patients, chemists could not care less. For them profits will be the only criteria of selling medicines." (Para 32)

9. "The Committee is aware that in its bid to help bring down healthcare costs the Union Health Ministry had recently issued directions to doctors in the Central Government-run hospitals to prescribe only generic drugs as far as possible and not branded drugs. In order to eliminate middlemen (C&F agents, distributors, wholesalers, retailers) the Committee recommends that the Governments, both at the Centre and the States procure generic drugs in bulk from manufacturers and dispense them directly to patients, through its health centres." (Para 33)

Action Taken by the Government

10. The Ministry in a consolidated reply to the above recommendations of the Committee as contained in paras 19, 21, 32 and 33 submitted the following information:–

A. Written Submissions

11. "In the context of the need for formulating an effective essential drug supply policy with the components as mentioned by the Committee, the issue was discussed in detail in the Conference of the State Health Ministers and Health Secretaries held on January 12-13, 2011 at Hyderabad. This policy also included the steps required to be taken for opening of more Jan Aushadhi Centres, at least one in a district across the States. During the Conference, the States were apprised of the experiments done in the States of Rajasthan, Bihar and Tamil Nadu for

promotion of generic drugs. The States agreed to take effective steps and prepare action plans for maximizing supply of generic drugs and also for opening up of more Jan Aushadhi Stores. As a follow-up to the decisions taken during the said Conference, Ministry of Health & Family Welfare has been pursuing the matter with the States. The States have been requested to formulate a time bound action plan for promotion of generic drugs with the following components and also an action plan for setting up of Jan Aushadhi Stores in districts:–

(a) Doctors in public health institutions must be instructed to prescribe generic drugs.

(b) The State must adopt a list of essential drugs. This may be based on the National List of Essential Medicines (NLEM).

(c) All drugs must be procured through open tender system.

(d) Low cost generic drugs must be distributed through Government drugs stores/ cooperative societies.

(e) A massive campaign must be mounted to generate public awareness for acceptance of generic drugs and removal of misgivings about generic drugs not being of standard quality."

12. "The Minister of Health & Family Welfare has also written to the State Health Ministers in this regard on 5th May, 2011."

13. "The responses from some of the States so far received are as under:–

(i) **Tamil Nadu** – The Tamil Nadu Government has stated that the Action Plan on opening of Generic Drugs stores will be finalized after the elections.

(ii) **Daman & Diu** – (a) Instructions have been issued to prescribe generic drugs in all public health institutions.

(b) A list of essential drugs has been adopted.

(c) All medicines are purchased from CPSUs. Open tender is called by generic names and procured as generic mcdicines.

(d) IEC activities shall be carried out during 2011-12 for which action plan is being proposed

(iii) **Gujarat** – Necessary action is being taken.

(iv) **Rajasthan** – (a) A circular has been circulated to all doctors to prescribe only generic medicines.

(b) Rajasthan has already adopted essential drug list, which has recently been updated.

(c) The procurement system is being revamped, and a Medical Services Corporation has been registered. The system will be fuctional *w.e.f.* 2nd October, 2011.

(d) An IEC campaign to popularize generic drugs and removal of misgivings about them is being planned and will be rolled out soon.

(v) **Union Territory of Dadra & Nagar Haveli** – (a) In Dadra & Nagar Haveli there is one Civil Hospital, one Community Health Centre, six Primary Health Centres and three Dispensaries. AIl the doctors have been instructed to prescribe generic drugs

and also all the purchases of drugs by the health department are on the basis of generic drugs only.

(b) The National List of Essential Medicines is being adopted by this UT Administration.

(c) All drugs are distributed through Civil Hospital, CHC, PHCs and dispensaries and are given free of costs.

(d) The department has been instructed to conduct a massive campaign for public awareness about generic drugs and acceptance of generic drug of standard quality and removing the tag of not of standard quality.

(vi) **Orissa** – Indian Red Cross Society, Orissa Branch, an international body with philanthropic credentials, has been given the charge of opening generic medicine stores in the state. In the first phase, it has been decided to open Jan Aushadhi outlets in all District Headquarters, Hospitals and 3 Government Medical College and Hospitals. As of now, Jan Aushadhi outlets have been opened at 13 places. Besides, 3 such stores are likely to be opened during May, 2011. Point-wise action plan for promotion of generic drugs is given below:

1. Doctors in public health institutions have been instructed to prescribe generic drugs. It has been discussed also in the GDMOs' conference.

2. The State has adopted a list of essential drugs in generic name. The present essential drug list 2009-10 contains 320 (310 drugs+10 combi packs) in generic. The essential drugs list is updated every 2-3 years as per the WHO model list and rational list of essential medicine.

3. Drugs are being procured through open tender system *i.e.* National competitive bidding, local small scale industries and DGS&D (CPSU) rate contract holders as per IPR resolution and Government of India guidelines from time to time.

4. Generic drugs are being procured by Government and distributed through Government stores.

5. Steps are being taken for public awareness campaign for use of generic drugs. Besides, Red Cross is also doing at their level."

14. "The Ministry is committed to pursuing this matter with the States on a regular basis. The Ministry will also continue to discuss the issue of promotion of generic drugs and impress upon the States to take immediate time bound steps in this regard, in every meeting of the States' Health Ministers and Health Secretaries."

15. "The Ministry has also taken a few steps at the Centre in this regard. Repeated circulars/ instructions have been issued to all Government hospitals and CGHS dispensaries to prescribe generic medicines to the maximum extent possible. Latest such circular/instructions have been issued on 19.5.2011. At the hospitals level also, circulars by Medical Superintendents of hospitals in Delhi have been issued from time to time encouraging/motivating doctors to prescribe generic drugs. Regular meetings are now being taken by Additional DG (Stores) in the Medical Stores Organisation (MSO) with the Government hospitals and CGHS to promote availability and prescription of generic drugs. In the last such meeting held on 11.5.2011, the representatives of Government hospitals were asked to make available generic medicines 24 hours a day through their pharmacy counters and also issue instructions to the doctors/specialists to prescribe generic medicines as well as monitor their compliance on a regular basis."

16. " AIIMS has also taken a decision at the level of its Governing Body in its meeting held on 27.11.2010 to start a 24x7 medicine outlet in their premises for providing generic medicines to patients. Further modalities are being worked out."

17. "The Ministry has now for the first time drawn up a common generic formulary for all Government Hospitals and CGHS Wellness Centers. The formulary contains 664 generic drugs which include all of 348 generic drugs included in the revised NLEM, 2011."

18. "At present, there is a rate contract for 127 number of generic drugs out of which 62 are reserved for Central Public Sector Enterprises (CPSEs). Necessary action has now been initiated to have a rate contract for additional 193 generic drugs. Once this rate contract is finalized, there will be a total of 320 generic drugs available for Government hospitals and CGHS Wellness Centres to be provided to patients."

19. "National Informatics Centre (NIC) has prepared a software to be used by all Government hospitals and CGHS Wellness Centres by which if doctors prescribe branded drugs, the printed prescriptions will contain not only prescribed branded drugs but also their generic equivalents. This is proposed to be tried initially on a pilot basis."

20. "The Medical Stores Organisation (MSO) has revised the Procurement and Operation Manual after a gap of 32 years. The Manual lays down detailed Standard Operating Procedures (SOPs) which will facilitate total e-procurement, quality assurance, adoption of good storage practices in respect of all medical stores. The manual will, *inter alia,* ensure procurement of quality generic drugs and thereby improve prescribing practices."

21. "The Ministry of Health and Family Welfare has proposed the Central Procurement Agency (CPA), as an autonomous society, and the proposal has been approved on 11.5.2011 by the Expenditure Finance Committee headed by Secretary (Expenditure), Ministry of Finance and this proposal will now be submitted to the competent authority for approval. Once CPA comes into being, use of generic drugs in Government hospitals, CGHS dispensaries and other hospitals/ dispensaries like those of Central Para Military Forces will be further streamlined and maximized through the centralized procurement of such generic drugs."

B. Submissions made during the course of Oral Evidence

22. The Committee not being happy with the above action taken reply called the Secretary of the Department to apprise it of the updated status of the steps taken to promote the use of generic drugs in the country. The Secretary, Department of Health and Family Welfare during the course of his deposition before the Committee on 3rd June 2011, reiterating the above status, made following additional submissions:

- ➢ At the behalf of the Government of India the Medical Council of India has included, as part of the UG pharmacology curriculum, the subjects of essential drugs, rational use of drugs and good prescribing habits.
- ➢ The Department of Health and Family Welfare is continuously taking up with the Department of Pharmaceuticals the issue of promotion of generic drugs and setting up of more Jan Aushadhi Stores.

23. Taking note of the submissions made in the Action Taken Note to the effect that in the meeting of the Drugs Consultative Committee held on 28.10.2010, the Department of Health and Family Welfare had suggested that the State Drugs Control Authorities may grant licenses for manufacturing of single drug formulations in generic names only to promote availability of generic drugs at affordable prices, the Committee asked the Drug Controller General of India (DCGI) to clarify whether this was legally tenable. The DCGI admitted before the Committee that it was not

legally tenable and that the Drugs and Cosmetics Act, 1940 would have to be amended to make this happen.

24. Apprising the Committee of the vision behind the Jan Aushadhi Programme, the Secretary, Department of Pharmaceuticals, during the course of his deposition before the Committee on 18th February 2011, had stated that all drugs sold in the country are generic drugs except 18 patented drugs. He had also stated that the generic drug is a non-patented drug and it can either be a branded generic drug or a non-branded generic drug. If a drug is not patented, it is generic, which means any company can manufacture it. He also stated that if people use unbranded generic drugs, the effect was the same but the price paid by them was just a fraction of the price of the branded drugs. He had further informed that it was in this context that the Jan Aushadhi Programme was started where it was decided that the Government would, alongwith the State Governments, NGOs and other sectors, set up the stores, preferably in locations like Government hospitals etc. and that these stores would be selling only unbranded generic drugs which would be manufactured by the Public Sector Pharma units. The Secretary (Pharmaceuticals) flagged the following facts about the Jan Aushadhi Programme:–

- ➢ There were a lot of issues in this programme concerning supply, distribution and production chains.
- ➢ A review has been undertaken and an integrated business plan is being prepared.
- ➢ The first objective is to cover three thousand subdivisions of the country within next three years.
- ➢ Each Sub-division would have one Jan Aushadhi Store located in the primary or the secondary hospital, whichever is available.
- ➢ A list of 350 medicines have been drawn up which will be kept by each store.
- ➢ A supply chain will be set up; there will be a stockist who will supply to the Jan Aushadhi outlet and he will take indent from the Store and send it to the Headquarters.
- ➢ There will be a production plan with the public sector companies like Hindustan Antibiotics, or IDPL and whenever they are not able to manufacture the medicines themselves, they get them contract manufactured from somewhere else.
- ➢ Each store will be subsidized for three years till it becomes viable on its own.
- ➢ A directory listing out all the branded generic drugs and their unbranded generic counterparts is being introduced.
- ➢ A big publicity programme like the Pulse Polio Programme is being budgeted to make people aware of the generic medicines.

25. Asked to explain the reasons behind the delay in promoting generic drug by opening more Jan Aushadhi Outlets, the Secretary, Department of Pharmaceuticals, during the course of his deposition before the Committee on 3rd June 2011, stated that his Department was preparing a revised business plan to expand the Jan Aushadhi programme in which 600 plus Jan Aushadhi stores are targeted to be established within the next two years, and 3000 stores in four years, depending on the response from the State Governments. He also informed that as on date 102 Jan Aushadhi Stores have already been set up. Mentioning about the constraints in opening more Jan Aushadhi outlets, the Secretary, (Pharmaceuticals) made the following submissions:–

- ➢ This programme is being implemented in conjuction with State Governments.

- ➢ In regard to the opening of Jan Aushadhi Stores, the appointment of operating agencies and to make sure that these operating agencies will not make use of these premises for promoting non-Jan Aushadi Drugs, the responsibility induding due diligence and vigilance are all with the State Governments.
- ➢ There were some deficiencies in the Programme concerning supply, distribution and production plans.
- ➢ A review of this programme was done and it was found that there was no proper supply chain and no proper assessment was available whether the public sector units could provide the exact quality of medicines required for a Jan Aushadhi store.
- ➢ The capabilities of the public sector pharma units to provide medicines have been worked out.
- ➢ The revised business plan concerning Jan Aushadhi is being discussed with Ministry of Finance and the differences have been narrowed down.
- ➢ Earlier it was planned to open six hundred outlets in one year; but keeping in view the slow responses being received from the State Governments, it may take two years to open 600 to 650 stores.
- ➢ A lot of cooperation from State Governments is needed for promotion of the Jan Aushadhi Programme.

26. In reply to a query regarding the status of revival of Public Sector Pharma Units, the Secretary (Pharmaceuticals) during his oral evidence before the Committee on 3rd June 2011, informed that the revival schemes of Hindustan Antibiotics and Bengal Chemicals have been approved and they were in the final stages of implementation. The implementation of revival scheme of Bengal Chemicals was facing some problems due to legal cases but the scheme should be implemented fully in three to four months' time. As regards the IDPL, the Secretary (Pharmaceuticals) informed that the revival scheme has been worked out and the Cabinet would be moved in two months time.

27. In reply to a query regarding the latest status of the Central/State Public Sector pharmaceutical units and proposal, if any, for their revival of Public Sector sick pharma units, the Ministry of Health and Family Welfare in a written submission dated the 10th August, 2011 informed that Karnataka Antibiotics and Pharmaceuticals Limited (KAPL), Bangalore and Rajasthan Drugs and Pharmaceuticals Ltd. (RDPL) Jaipur are profit making Mini Ratna Central PSUs and Rs.7.10 crore and Rs.2.00 crore have been sanctioned respectively for their modernization/upgradation and making them Schedule M and WHO-GMP compliant. The Ministry also *inter-alia* informed that for the revival/modernization of (i) Hindustan Antibiotics Ltd. (HAL), Pimpri, Pune and (ii) Bengal Chemicals and Pharmaceuticals (BCPL), Kolkata, Government of India had sanctioned Rs.3017 crore, and Rs.207.19 crore respectively. In respect of the Indian Drugs and Pharmaceuticals Ltd. (IDPL), Gurgaon, it was informed that IDPL was formally declared sick by the Board for Industrial and Financial Reconstruction in August, 1992 and that after failure of earlier revival packages, a modified revival proposal was put up before the Cabinet which referred it to a Group of Ministers (GoM) and as per the recommendation of the GoM, a Detailed Project Report was being prepared by an Expert Consultant, after finalization of which it would be put up before the Cabinet for consideration.

28. In a written submission made subsequently, the following details regarding production and sales turnover in respect of the Karnataka Antibiotics and Pharmaceuticals Limited (KAPL), Bangalore, Rajasthan Drugs and Pharmaceuticals Limited (RDPL), Jaipur, Hindustan Antibiotics Limited (HAL), Pimpri, Pune and Indian Drugs and Pharmaceuticals Limited (IDPL), Gurgaon were also furnished:–

Production and Sales Turnover of Karnataka Antibiotics and Pharmaceuticals Limited

(*Rs. in crore*)

Year	2007-08	2008-09	2009-10	2010-11*
Production	226.33	250.92	218.75	242.48
Sales Turnover	196.45	225.01	212.81	213.26

* Provisional

Production and Sales Turnover of RDPL

(*Rs. in crore*)

Year	2007-08	2008-09	2009-10	2010-11*
Production	81.86	71.53	76.13	83.80
Sales Turnover	94.33	80.76	85.35	80.68

* Provisional

Production and Sales Turnover of HAL, Pimpri, Pune

(*Rs. in crore*)

Year	2007-08	2008-09	2009-10*	2010-11*
Production	119.81	155.00	123.16	84.92
Sales Turnover	106.59	147.39	118.26	95.14

Production and Sales Turnover of IDPL, Gurgaon

(*Rs. in crore*)

Year	2007-08	2008-09	2009-10*	2010-11*
Production	62.13	93.20	108.10	59.75
Sales Turnover	56.70	83.57	96.59	60.00

*Provisional

Further Recommendation

29. **The Committee is constrained to note the snail's pace of progress made in setting up Jan Aushadhi Stores in the country. The Committee is pained to observe the lackadaisical approach and lack of sense of urgency on the part of the Department of Pharmaceuticals in ironing out the hindrances in establishing Jan Aushadhi Stores. The Committee also observes that between the 18th February, 2011 when the Secretary (Pharmaceuticals) first deposed before the Committee and the 3rd June, 2011 when the Committee last interacted with him, there was little progress in addressing the inadequacies**

from which the Jan Aushadhi Programme suffers. Though assurances have been made before the Committee to revamp the Jan Aushadhi edifice by way of finalising an integrated business plan, lack of any deadline for implementation of the integrated business plan gives an impression that the issue of promotion of generic drugs is being soft-pedalled. The Committee takes note of the fact that the issue of drug prices is intrinsically linked with the promotion of generic drugs and that in the Conference of State Health Ministers and Health Secretaries held on 12-13 January, 2011, the States have agreed to promote Jan Aushadhi Stores. The Committee, therefore, recommends that the Department of Pharmaceuticals should take credible initiatives towards settling the problems of supply, distribution and production chains and implementing the integrated business plan in a time-bound manner. The Committee desires to be kept apprised of the progress made in this regard.

30. **The Committee observes that the Public Sector Pharma Units have a vital role to play in checking the possible monopolistic practices by the private sector drug companies and ensuring availability of quality drugs at reasonable prices to the people. It is in this context that the revival plan/modernization of public sector pharma units are of utmost importance and relevance. However, the Committee is constrained to observe that the nodal department (in this case the Department of Pharmaceuticals) seems be in the grip of policy inertia which is evident from the fact that though IDPL was declared sick by BIFR in August, 1992 and almost 19 years have elapsed since then, yet its revival plan is still hanging fire. It is difficult to fathom how the Department of Pharmaceuticals will be able to work out a robust integrated business model for supply of generic drugs through Jan Aushadhi Stores if the revival plans are not implemented. The Committee is convinced that the imbalance of absence of low cost medicines cannot be mitigated without the participation of Central Pharma PSUs. The Committee, therefore, recommends with all the power at its command that the nodal Department of Pharmaceuticals shed its indecisiveness and take all possible measures to speed up the revival of all Central Pharma Units, so that the all-important objective of access to affordable and quality medicines to all could be realized. The Committee would like to be kept apprised of the progress made towards implementation of the revival plan of all public sector sick drug companies.**

31. **The Committee is constrained to observe that the production and sales turnover figures of KAPL and RDPL are more or less static in value terms for the years 2007-08, 2008-09 and 2009-10. Since there must have been some upward movement of prices since 2006, the Committee apprehends that the above figures are indicative of de-growth in volume terms. The Committee desires that Government may look into the matter and steps may be taken to improve the condition in real terms.**

32. **Scrutiny of the production and sales figures of HAL and IDPL for the years 2008-09, 2009-10 and 2010-11 reveal that the figures have actually gone down, which is a matter of serious concern for the Committee. The Committee strongly recommends that immediate efforts may be made to reverse the trend and improve the performance.**

33. **The Committee is amazed to note that the Department of Health and Family Welfare suggested to the State Drugs Control Authorities to grant licenses for manufacture of single drug formulations in generic name only, though it knew fully well that such an action on the part of the State Drug Licensing Authorities will not enjoy legal sanction till the Drugs and Cosmetics Act is amended with respect to the labeling requirements. The Committee would like to counsel the Department to focus on a more structured and reasoned policy for promotion of generic drugs than such a bizarre policy which is unlikely to result in positive outcomes.**

34. **The Committee notes that some forward movement has been reported towards formulating an effective essential drug supply policy which is evident from the fact that in the Conference of the State Health Ministers and Health Secretaries held on January 12-13, 2011 at Hyderabad, the States agreed to take effective steps in this direction. The Committee also observes that as of now only six States/Union Territories have given their responses on promotion of generic drugs and formulation of an essential drug supply policy. The Committee feels that non-receipt of the comments from other States is very serious and the Central Government should pursue the matter with all the States. The Committee expresses its dismay over the fact that major States like West Bengal, Jharkhand, Uttar Pradesh, Punjab, Madhya Pradesh, Chhattisgarh, Kerala, Karnataka and Andhra Pradesh have not responded. The Central Government may pursue the matter with them. The Committee desires that the Ministry may identify the shortcomings in the States that have not formulated the policy and commented on the Model policy and help them in this regard. The suggestions that were made in the above conference held at Hyderabad may be made use of and the Ministry may also pursue the implementation of the suggestions made therein.**

35. **The Committee notes that the Department of Health and Family Welfare has taken a number of initiatives towards promoting generic medicines like – motivating the doctors in the Government hospitals and CGHS dispensaries to prescribe generic medicines to the maximum extent possible, opening of a 24x7 medicine outlet in the premises of AIIMS, drawing up a common generic formulary containing 664 generic drugs, rate contract for additional 193 generic drugs, preparing a software containing generic equivalents of prescribed branded medicines and the revision of the Procurement and Operation Manual. Though the Committee welcomes the above initiatives of the Department, it has a word of caution in this regard. As is evident from para 32 of the Committee's 45th Report, going for a "generic only" prescription policy has its flip side as it would shift the power of prescription from doctors to the chemists and such a scenario would be worse than the current situation for the reasons outlined in para 32 of the 45th Report. The Committee, therefore, recommends that instead of focusing on a single strategy, the Department should follow a combination of policies including pharmaceutical pricing regulations for ensuring availability and afford ability of quality medicines, both generic and branded.**

36. **The Committee welcomes the proposal of setting up the Central Procurement Agency as an autonomous society as it can help control drug prices through procurement process. The Department may move the Cabinet for its approval with a sense of urgency.**

Recommendations/Observations

37. In paras 22, 26 and 27 of its 45th Report, the Committee had dealt with the issues of selling new patented drugs at exorbitant prices, constitution of a High Powered Inter-Ministerial Coordination Committee and giving wide publicity to the efficacy of generic medicines so as to dispel the apprehensions of the general public about generic drugs not being of good quality. For the facility of easy reference, the above paras are quoted below:–

38. "The Committee noted that apart from NPPA and DCGI, import and export policies of drugs are looked after by the Ministry of Commerce, fiscal matters by the Ministry of Finance and the policy effects on small scale pharma units is dealt with by the Ministry of Small and Medium Enterprises (MSME). At present, NPPA has no jurisdiction over the pricing of new patented medicines with the result that they are being sold at exorbitant prices, many of them by importers. The Committee urges the Government to address this issue without any further delay". (Para 22)

39. "The Committee welcomes the initiative in this regard and sincerely hopes that the constitution of the Inter-Ministerial Coordination Committee would not only ensure availability of drugs at fair prices but also result in better coordination between the office of DCGI and the NPPA. The Committee desires to be kept apprised of the findings of the Inter-Ministerial Coordination Committee and the action taken thereon after conclusion of the consultation in this regard". (Para 26)

40. "Since all drugs whether branded, generic or branded generic, manufactured and/or imported for sale and distribution in the country, are required to conform to the same quality parameters listed in the Drugs and Cosmetics Rules, the Committee would like the Inter-Ministerial Coordination Committee (IMCC) to give wide publicity to this fact, so that the apprehensions of general public fueled and fanned by interested quarters about generic drugs not being of good quality could be dispelled". (Para 27)

Action Taken by the Government

(A) Written Submissions

41. In a consolidated reply to the above recommendations of the Committee as given in paras 22, 26 and 27 of the 45th Report, the Ministry of Health and Family Welfare made the following submissions in the ATN:–

42. "The Ministry of Health and Family Welfare has constituted on 31.3.2011 a Task Force for formulating a long term policy and strategy for strengthening of the Drug Sector in the country under the chairmanship of Secretary, Department of Health Research and Director General, Indian Council of Medical Research (ICMR). The terms of reference of the Task Force are as under:–

(i) Evolve a short, medium and long term policy and strategy to make India a hub for drug discovery, research and development.

(ii) Formulate and recommend strategies to further the interests of Indian pharmaceutical industry in the light of issues related to intellectual property rights and also strategies to capitalize on the opportunity of drugs worth 60-80 billion US dollars going off-patent over the next 5 years.

(iii) Evolve and suggest policy options/measures to assure National Drugs Security *i.e.*

- Promoting indigenous production of bulk drugs.
- Preventing takeover of Indian pharma companies by Multinational Corporations (MNCs). Pricing of drugs.
- Promotion of generic drugs and adequate availability of quality generic drugs at affordable prices.

(iv) Recommend measures to tackle the problem of spurious and adulterated drugs.

(v) Devise roadmaps for implementation of all recommended strategies and measures".

43. "The Task Force is required to submit its report within a period of 3 months from the day of its 1st meeting. The 1st meeting of the Task Force is being convened very soon".

44. "A High Powered Inter-Ministerial Coordination Committee (HPIMCC) headed by Secretary, Department of Pharmaceuticals in its meeting held on 29.3.2010 decided to constitute two Working Groups to look into matters of price and quality aspects of medicines and the two Working Groups were formed *vide* two separate O.Ms. dated the 25th May, 2010. The Department of Pharmaceuticals has been asked to indicate the present status of the recommendations to be made

by these two Working Groups. The Department of Pharmaceuticals has also been requested to convene the next meeting of the Inter-Ministerial Coordination Committee".

B. Submissions made during the course of Oral Evidence

45. The Secretary, Department of Health and Family Welfare during the course of his deposition before the Committee on 3rd June, 2011 informed the Committee that the first meeting of the Task Force was scheduled to be held on the 6th June, 2011.

46. On being enquired about the status of submission of reports by the High Powered Inter-Ministerial Coordination Committee (HPIMCC) constituted on 8th March, 2011 and the two working Groups which were formed by the HPIMCC on 25th May, 2010 and which were to submit their reports within a period of 90 days, the Secretary (Pharmaceuticals) informed the Committee on 3rd June, 2011 that the two working Groups had submitted their Reports which would be considered by the HPIMCC and their inputs used while drafting the final report of the HPIMCC. He also informed that it would take six months to finalise the new pharmaceutical policy.

47. Asked to elaborate on the steps taken to address the issue of new patented medicines being sold especially by importers at exorbitant prices, the Secretary (Pharmaceuticals) stated that the patented medicines are not under price control. He further stated that the prices of non-patented imported drugs which are included under DPCO, are controlled. On being asked as to why there was no mechanism to ensure that the price of the same patented drug was not significantly high in India than in other countries and international manufacturers do not sell their drugs in India at supernormal profits, he replied that no country regulates cost pricing in the open market; however such drugs can be purchased at lower prices by the government for its public health programmes. The Secretary (Pharmaceuticals) also informed that the price regulation of patented imported drugs would be part of the New Pharmaceutical Policy which would be finalized within a period of six months.

Further Recommendation

48. **Now that the Working Groups have already submitted their reports, the Committee recommends to the Department of Pharmaceuticals to finalise the New Pharmaceutical Policy without further loss of time. The Committee desires to be kept apprised of the updated status in this regard.**

49. **The Committee would also like to be kept informed of the findings of the Task Force constituted by the Ministry of Health and Family Welfare and action taken thereon.**

50. **The Committee notes that as of now there is no mechanism in place to regulate the prices of new patented drugs which are imported in the country and sold at supernormal profits, whereas prices of the same medicines are considerably lower in other countries. The Committee does not accept the submission made by the Secretary (Pharmaceuticals) that there is no price control of a patented drug for open market. The Committee would like to observe that India as a sovereign country has every right to decide the prices of a drugs which are sold in the open market. The Committee therefore recommends to evolve an effective mechanism to control prices of imported patented drugs being sold in Indian Market.**

51. **The Committee also takes note of the submissions of the Secretary (Pharmaceuticals) to the effect that the issue of price regulation of imported molecules being sold in the country at high prices will be taken care of in the New Pharmaceutical Policy which is currently under finalization. The Committee feels that the issue at hand is**

too urgent to be left open-ended and, therefore, recommends that Department of Pharmaceuticals resolve this issue within a period of six months. The Committee would also like the Department to put in place an effective mechanism to enable the use of international price benchmarks in such cases and limit the price of an imported drug by comparison with the price of the same drug in other countries and thus check windfall profits made by importers on selling imported molecules at exorbitant prices in the country.

Recommendations/Observations

52. In para 31 of its 45th Report, the Committee had highlighted the issue of unethical promotion of medicines by doctors and drug companies. The said para is quoted below for ready reference:–

53. "The Committee also notes that despite there being a code of ethics in the Indian Medical Council Rules introduced in December 2009 forbidding doctors from accepting any gift, hospitality, trips to foreign and domestic destinations etc. from healthcare industry, there is no let-up in this evil practice and the pharma companies continue to sponsor foreign trips of many doctors and shower with high value gifts like air conditioners, cars, music systems, gold chains etc. to obliging prescribers who then prescribe costlier drugs as *quid pro quo*. Ultimately all these expenses get added up to the cost of drugs. The Committee's attention was drawn to a news item in Times of India dated July 1, 2010 giving specific instances of violations of MCI code. The Committee calls upon the Government to take strict and speedy action on such violations. Since MCI has no jurisdiction over drug companies, the Government should take parallel action through DCGI and the Income Tax Department to penalize those companies that violate MCI rules by cancelling drug manufacturing licences and/or disallowing expenses on unethical activities". (Para 31)

Action Taken by the Government

54. In response to the above recommendation the Ministry made the following submissions in the ATN:–

(A) Written Submissions

55. "The Ministry has been pursuing with the Medical Council of India (MCI) to strengthen the monitoring mechanism of the Council so that necessary action could be taken against doctors for violation of the IMC (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2009 in general and the newly inserted clause 6.8 in particular which states that a medical professional shall not endorse any drug or product of the industry publicly".

56. "The Ministry has also requested on 30.3.2011 the Ministry of Corporate Affairs to insert in their voluntary guidelines on Corporate Social Responsibility (CSR) provisions similar to those in the IMC (Professional Conduct, Etiquette and Ethics) Regulations 2002 as amended in 2009, as and when they revise the voluntary guidelines on CSR".

57. "Department of Pharmaceuticals has been asked to indicate the current status of Uniform Code of Pharmaceutical Marketing Practices (UCPMP)".

58. In reply to a question regarding taking action through the Drug Controller General of India and Income Tax Department to penalize drug companies which indulge in unethical promotion of drugs, the Department of Health and Family welfare *vide* its O.M. dated 10th August, 2010 *inter alia* informed that the Drugs and Cosmetics Act was essentially an Act to regulate quality of drugs marketed in the country and that the professional conduct of Pharma companies did not fall under the purview of the said Act. The Department also informed that as regards controlling their conduct through the Income Tax Act, the Department of Revenue had been requested to examine this for appropriate action.

(B) Submissions made during the course of Oral Evidence

59. On being asked about the specific action taken by the Medical Council of India against the doctors who violate the code of conduct as laid down in the Medical Council of India Rules and accept high value gifts from Pharma Companies including sponsoring foreign trips of many doctors, the Secretary, Department of Health and Family Welfare, during his oral evidence before the Committee on 3rd June, 2011, informed that the Medical Council of India had been asked to take action in the matter. The representative of the Medical Council of India, Dr. Sangeeta Sharma, who was present during the meeting on 3rd June, 2011, informed the Committee that action had been taken in seven cases of violation of the code of conduct of M.C.I. The cases cited by Dr. Sangeeta Sharma related to sponsoring of foreign trips of 300 doctors by the pharmaceutical industry in the name of a conference, endorsement of certain products by the Indian Medical Association and distribution of gold coins to doctors by a pharmaceutical company. Dr. Sangeeta Sharma also informed the Committee that as of now the M.C.I. has no jurisdiction over the pharmaceutical companies which indulge in such bribe-giving. She also stated that with a view to checking this evil practice, instructions had been issued regarding the procedure to be followed for sponsoring CME, mentioning of PAN Card Number for receiving money for attending Conferences and audit of such conferences, and posting of reports of the conferences on the website.

60. Asked about the status of progress of finalization of the Uniform Code for Pharmaceutical Marketing Practices to curb the unethical practice of bribing by pharma companies, the Secretary (Pharmaceuticals), during his oral evidence before the Committee on 3rd June, 2011, informed that the Code had been finalized and put on the Internet for responses from stakeholders. He further stated that a month's time had been given for furnishing views/suggestions on the Code and the Department would be able to notify the uniform Code in a month and a half. On being asked as to whether the proposed Uniform Code was voluntary or mandatory, he informed that it was voluntary. Asked about the rationale behind making the Code voluntary and not mandatory, the Secretary (Pharmaceuticals) explained that the Code would be a voluntary one initially and its implementation would be tracked over a period of six months and if its implementation was not satisfactory during that period, the Department of Pharmaceuticals would make it a statutory code.

Further Recommendations

61. **The Committee observes that serious anomalies exist in the law inasmuch as while there is a code of conduct for doctors forbidding them from accepting any gift, hospitality, trips to foreign and domestic destinations, no such legal provisions for penalizing pharma companies indulging in the unethical practices of bribing the doctors by way of offering expensive gifts, cash payments or sponsoring of pleasure trips, are in force. Keeping in view the fact that it is no secret that promotional costs are loaded into the price of prescription drugs and constitute a major part of the price of the drugs, the Committee welcomes the move towards framing a Uniform Code of Pharmaceutical Marketing Practices. However, the Committee is at a loss to understand as to why the Code has been made a voluntary code and not a statutory one. The Committee has been given to understand that the voluntary code has generally not been successful in curbing unethical practices and off-label promotion of drugs. The Committee notes that the Secretary (Pharmaceuticals) was not able to offer any valid reason for not making the Uniform Code a statutory provision.**

62. **The Committee therefore, recommends that the Department of Pharmaceuticals should take decisive action in making the Uniform Code mandatory so that effective check could be put on huge promotional costs and the resultant impact of the add-on costs on medicine prices.**

63. **The Committee observes that as of now the onus of checking unethical promotion of drugs by pharma companies lies exclusively with the Department of Pharmaceuticals (which is primarily mandated to act as a catalyst for the growth of the pharma industry in the country) and the Ministry of Health and Family Welfare has no role to play in this matter, though protection of patients is the job of the latter. The Committee, therefore, fails to understand, much less appreciate, the reasons behind the Department of Pharmaceuticals dealing with this issue exclusively, though Code of Conduct in pharmaceutical marketing affects both doctors and patients. Keeping this in view and also the fact that all over the world, such activities are under the National Drug Regulatory Authorities, the Committee, recommends that the Ministry of Health and Family Welfare may also be involved in implementation of Code of Conduct in Pharmaceutical Marketing.**

64. **After the presentation of the report, the only action taken by the Department of Health and Family Welfare was that it had requested the Department of Revenue to examine this issue of penalizing drug companies indulging in unethical promotion of drugs. The Committee is not aware of any further development in the matter.**

65. **The Committee, therefore, recommends that the Department of Health and Family Welfare actively pursue the matter with the Department of Revenue.**

Recommendations/Observations

66. In paras 34, 35 and 36 of its 45th Report, the Committee had made recommendations regarding putting a cap on profit margins of medicines. The said paras are reproduced below for ready reference:–

67. "One option for making available affordable medicines put forth before the Committee was to cap the profit margin of all medicines irrespective of whether they are under DPCO or not. This step would do away with the need of monitoring prescriptions, identifying the manufacturers supplying low-priced medicines and without any need to prefer generic over branded products. If fixation of MRP is done by NPPA based on a fair, transparent system keeping interests of all stakeholders in mind nearly all issues on pricing would get resolved. This system is already in vogue in many other fields such as electricity rates, bus and taxi fares, interest rates, insurance premium just to mention a few. Lastly, with the floating of an open tender in the market, all drug manufacturers/stockiest would come forward with the offer of lowest possible rates". (Para 34)

68. "The Committee is aware that a legal framework is available by way of Essential Commodities Act, 1956 under which the Government can put a cap on profitability. The Committee has also been informed that in the original Drug Price Control Order, there was a proposal that in addition to price control on individual drugs, there should be a cap on the overall profitability of the drug manufacturers. The objective was to discourage manufacturers to shift from Price-Controlled (less profitable) to uncontrolled (hugely profitable) medicines. The proposal was, however, never implemented. Taking into account all the above facts, the Committee, recommends that the Department of Health and Family Welfare in coordination with the Department of Pharmaceuticals immediately move the Inter-Ministerial Coordination Committee and initiate a process of examining the issue of putting a blanket cap on profit margins of all medicines across board. The Committee desires to be kept apprised of the action taken in this regard". (Para 35)

69. "The Committee is, however, of the considered view that given the current ground realities in the country where more than 80 per cent population is dependent on private medical care and nearly 45 crore people live below the poverty line, the most effective and direct approach would be to put a blanket cap on profit margins of all medicines across the board. Medicines are the only item where the decision to buy is not taken by the purchaser but by a third party *i.e.*, doctor.

Therefore, if prescribers and producers join hands and take advantage of a patients' helplessness, only State can stop them". (Para 36)

Action Taken by the Government

70. In reply to the above recommendations, the Ministry made the following submission in the ATN:–

A Written Submissions

71. "The Department of Pharmaceuticals has constituted two Working Groups to look into the matter of pricing and quality aspects of medicines which will give their recommendations for consideration by the High Powered Inter-Ministerial Coordination Committee".

B. Submission made during the course of Oral Evidence

72. The Secretary (Pharmaceuticals) during his deposition before the Committee on 3rd June, 2011, informed that the two Working Groups had submitted their Reports and the same would be considered by the High Powered Inter-Ministerial Coordination Committee while drafting its final report.

Further Recommendations

73. **The Committee observes that almost a year has elapsed since the Committee presented its 45th Report to the Parliament but except the constitution of a Working Group to look into the matter of pricing of medicines no forward movement on putting a cap on the profit margin of medicines has been reported.**

74. **It has been a well-documented fact in India that high medicine prices are one of the biggest obstacles towards access to affordable treatment. Availability of the quality-assured affordable medicines is a vital prerequisite for affordable treatment. But given the financial profile of the general masses in the country, leaving the prices of medicines unregulated and entirely to the mercy of the market economy is unlikely to achieve the public health objectives. In such a scenario, expecting the free market system to ensure access to essential medicines is unrealistic. The Committee, therefore, reiterates its earlier recommendation of initiating the process of examining the issue of a blanket cap on profit margins of all medicines across the board. The Committee also recommends to expedite the matter.**

Recommendations/Observations

75. In para 37 of its 45th Report, the Committee had dealt with the issue of takeover of Indian pharma companies by MNCs which is reproduced below for ready reference:-

76. "Another pertinent issue that attracted the attention of the Committee was a news-item dated 31st May, 2010 published in the Hindustan Times which highlights the following issues:

- 61 drugs worth over $ 80 billion are going off patent of the US Patent and Trademark Office between 2011 and 2013 making it possible for domestic pharma companies in India to produce cheaper versions of off-patent drugs."

77. "However, promoters of some of the Indian pharma companies like Piramal Healthcare, Ranbaxy, Shanta Biotech and Dabur Pharma have already sold their controlling shares to US, Japanese and German MNCs. Many other drug manufacturers are reportedly interested in similar

disinvestment. These developments would result in MNCs gaining market supremacy and essential medicines are bound to become costlier. The Committee would appreciate if the Ministry of Health and Family Welfare takes up this issue with the Ministry of Chemicals and Fertilizers without any delay to come up with policy options to ensure that major Indian pharma companies remain in Indian hands". (Para 37)

Action Taken by the Government

78. In response to above recommendation, the Ministry informed the following in the ATN:–

A. Written Submissions

79. "The Ministry has requested the Department of Industrial Policy and Promotion in the Ministry of Industry and Commerce to revisit the FDI policy in pharmaceutical sector emphasizing that there is a strong case of bringing FDI in pharma sector to the FIPB route in respect of brown field projects. The DIPP has agreed with the views of the Ministry. The matter is under further consideration of the Government".

B. Written Submissions

80. In reply to a question regarding the outcome of the study conducted by the Department of Commerce to look into the impact of recent takeovers on the domestic pharmaceutical industry, it was informed by the Ministry of Health and Family Welfare *vide* its communication dated the 10th August, 2011 that the Department of Commerce has entrusted the task of conducting the study to M/s Ernst and Young which was yet to complete the study.

B. Submissions made during the course of Oral Evidence

81. On being asked to acquaint the Committee with the action taken to check the trend of takeovers of Indian Pharma Companies by foreign Multinationals, the Additional Secretary, Department of H&FW, during the course of his deposition before the Committee on the 18th February, 2011, informed that the matter was taken up with the nodal department, namely, the Department of Industrial Policy and Promotion (DIPP) in a meeting held on 1st February, 2011. He further stated that the Department of Health and Family Welfare was able to convince the DIPP that there was a need to revisit the Foreign Direct Investment (FDI) policy in the pharma sector so that the trend of takeover of Indian Pharma companies by MNCs did not continue. On being asked to specifically indicate the decision taken in the meeting held on the 1st February, 2011, he replied that it was decided that there was a need to revisit the FDI policy in the pharma sector. He further elaborated that there was broad understanding in the meeting that the automatic route with 100 per cent FDI can continue in the green-field project; however, if the ownership of the brown field is getting shifted to foreign residents, such cases will not follow the automatic route, but come to the Foreign Investment Promotion Board so that the Government can have an opportunity to look at each case on a case-by-case basis with a view to taking a decision on allowing or otherwise, a takeover.

82. The Committee has been given to understand that during the last five years, a number of big Indian drug manufacturing companies have been taken over by the foreign multi-national companies. All those Indian Pharma Companies were engaged in production of a considerable quantity of generic drugs. Acquisition of the above companies by the foreign multi-national pharma companies would ultimately push up the prices of essential drugs considerably in the domestic market and as a result thereof, it would have an adverse impact on the country health sector. The Committee was further informed that impact of this trend of acquisition would be visible when

61 drugs worth over $80 billion would go off the patent list in USA between 2011 and 2013. Once the above drugs go off the patent list, the Indian Pharma Companies would be in a position to produce their cheaper generic variants in bulk quantity. As a result of the acquisition of the above domestic Pharma Companies as well as those likely to be acquired in the near future by the foreign multi-nation companies, these drugs would be sold at considerably higher side and it would adversely affect the Government's efforts to make available generic drugs at affordable prices against their branded counterparts.

Further Recommendations

83. **The Committee had recommended preventing takeover of domestic companies by MNCs and thus preserving in-house manufacturing capability in the country. Precious time has been lost due to delay on part of the Government to act in this regard and many more Pharma companies have since been taken over since the recommendation was made by this Committee. Even though the Committee feels the ideal route for regulating Foreign Direct Investment (FDI) in brown-field Pharma projects would have been through the FIPB, the Government in its wisdom has decided to achieve this through subjecting all such transactions to the scrutiny of the Competition Commission of India (CCI) after making necessary provisions in the operating norms to accommodate such transactions. The Committee partIy welcomes this move as it feels that such a step would help create some system of checks and balances and therefore address public health requirements in India. At the same time the Committee observes that since most of such Mergers and Acquisitions in Indian Pharma Sector are done through Special Purpose Vehicles (SPVs), appropriate mechanisms will need to be put in place to strengthen CCI and enable it to oversee the FDI in the Indian brown-field pharma companies without any threshold limit to be effective. The Committee desires to be apprised of the changes made in rules and regulations governing CCI to facilitate oversight by the CCI and check collusion and unfettered acquisition of Indian pharma companies.**

84. **The Committee feels that the country holds a strong position in producing generic drugs. Besides, the country has a strong distribution network not only in the country but also in other developing and underdeveloped countries. The Committee, therefore, strongly recommends that the Government should make all-out efforts to arrest the trend of acquisition of domestic pharma companies by the foreign multi-national companies. Besides, no stone should be left unturned towards developing and gearing up all the public sector pharma companies for production of cheaper quality generic drugs by giving them full functional autonomy and adequate financial support so that requirement of the country's public health sector may be met and the likely impact of the above acquisition of the domestic companies is neutralized.**

85. **The Committee, therefore, recommends with all the power at its command that the Ministry of Health and Family Welfare in consultation with the other Ministries/ Departments involved address this issue as a matter of top priority and revisit the FDI policy at the earliest.**

86. **The Committee while welcoming the move of conducting a study to assess the impact of takeovers on the domestic pharmaceutical industry recommends that keeping in view the urgency of the issue, the study may be completed at the earliest.**

CHAPTER-IV

RECOMMENDATIONS/OBSERVATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT ARE STILL AWAITED

-NIL-

RECOMMENDATIONS/OBSERVATIONS — AT A GLANCE

The Committee is constrained to note the snail's pace of progress made in setting up Jan Aushadhi Stores in the country. The Committee is pained to observe the lackadaisical approach and lack of sense of urgency on the part of the Department of Pharmaceuticals in ironing out the hindrances in establishing Jan Aushadhi Stores. The Committee also observes that between the 18th February, 2011 when the Secretary (Pharmaceuticals) first deposed before the Committee and the 3rd June, 2011 when the Committee last interacted with him, there was little progress in addressing the inadequacies from which the Jan Aushadhi Programme suffers. Though assurances have been made before the Committee to revamp the Jan Aushadhi edifice by way of finalising an integrated business plan, lack of any deadline for implementation of the integrated business plan gives an impression that the issue of promotion of generic drugs is being soft-pedalled. The Committee takes note of the fact that the issue of drug prices is intrinsically linked with the promotion of generic drugs and that in the Conference of State Health Ministers and Health Secretaries held on 12-13 January, 2011, the States have agreed to promote Jan Aushadhi Stores. The Committee, therefore, recommends that the Department of Pharmaceuticals should take credible initiatives towards settling the problems of supply, distribution and production chains and implementing the integrated business plan in a time-bound manner. The Committee desires to be kept apprised of the progress made in this regard. (Para 29)

The Committee observes that the Public Sector Pharma Units have a vital role to play in checking the possible monopolistic practices by the private sector drug companies and ensuring availability of quality drugs at reasonable prices to the people. It is in this context that the revival plan/modernization of public sector pharma units are of utmost importance and relevance. However, the Committee is constrained to observe that the nodal department (in this case the Department of Pharmaceuticals) seems be in the grip of policy inertia which is evident from the fact that though IDPL was declared sick by BIFR in August, 1992 and almost 19 years have elapsed since then, yet its revival plan is still hanging fire. It is difficult to fathom how the Department of Pharmaceuticals will be able to work out a robust integrated business model for supply of generic drugs through Jan Aushadhi Stores if the revival plans are not implemented. The Committee is convinced that the imbalance of absence of low cost medicines cannot be mitigated without the participation of Central Pharma PSUs. The Committee, therefore, recommends with all the power at its command that the nodal Department of Pharmaceuticals shed its indecisiveness and take all possible measures to speed up the revival of all Central Pharma Units, so that the all important objective of access to affordable and quality medicines to all could be realized. The Committee would like to be kept apprised of the progress made towards implementation of the revival plan of all public sector sick drug companies. (Para 30)

The Committee is constrained to observe that the production and sales turnover figures of KAPL and RDPL are more or less static in value terms for the years 2007-08, 2008-09 and 2009-10. Since there must have been some upward movement of prices since 2006, the Committee apprehends that the above figures are indicative of de-growth in volume terms. The Committee desires that Government may look into the matter and steps may be taken to improve the condition in real terms. (Para 31)

Scrutiny of the production and sales figures of HAL and IDPL for the years 2008-09, 2009-10 and 2010-11 reveal that the figures have actually gone down, which is a matter of serious concern for the Committee. The Committee strongly recommends that immediate efforts may be made to reverse the trend and improve the performance. (Para 32)

The Committee is amazed to note that the Department of Health and Family Welfare suggested to the State Drugs Control Authorities to grant licenses for manufacture of single drug formulations in generic name only, though it knew fully well that such an action on the part of the State Drug Licensing Authorities will not enjoy lepal sanction till the Drugs and Cosmetics Act is amended with respect to the labeling requirements. The Committee would like to counsel the Department to focus on a more structured and reasoned policy for promotion of generic drugs than such a bizarre policy which is unlikely to result in positive outcomes. (Para 33)

The Committee notes that some forward movement has been reported towards formulating an effective essential drug supply policy which is evident from the fact that in the Conference of the State Health Ministers and Health Secretaries held on January 12-13, 2011 at Hyderabad, the States agreed to take effective steps in this direction. The Committee also observes that as of now only six States/Union Territories have given their responses on promotion of generic drugs and formulation of an essential drug supply policy. The Committee feels that non-receipt of the comments from other States is very serious and the Central Government should pursue the matter with all the States. The Committee expresses its dismay over the fact that major States like West Bengal, Jharkhand, Uttar Pradesh, Punjab, Madhya Pradesh, Chhattisgarh, Kerala, Karnataka and Andhra Pradesh have not responded. The Central Government may pursue the matter with them. The Committee desires that the Ministry may identify the shortcomings in the States that have not formulated the policy and commented on the Model policy and help them in this regard. The suggestions that were made in the above conference held at Hyderabad may be made use of and the Ministry may also pursue the implementation of the suggestions made therein. (Para 34)

The Committee notes that the Department of Health and Family Welfare has taken a number of initiatives towards promoting generic medicines like – motivating the doctors in the Government hospitals and CGHS dispensaries to prescribe generic medicines to the maximum extent possible, opening of a 24x7 medicine outlet in the premises of AIIMS, drawing up a common generic formulary containing 664 generic drugs, rate contract for additional 193 generic drugs, preparing a software containing generic equivalents of prescribed branded medicines and the revision of the Procurement and Operation Manual. Though the Committee welcomes the above initiatives of the Department, it has a word of caution in this regard. As is evident from para 32 of the Committee's 45th Report, going for a "generic only" prescription policy has its flip side as it would shift the power of prescription from doctors to the chemists and such a scenario would be worse than the current situation for the reasons outlined in para 32 of the 45th Report. The Committee, therefore, recommends that instead of focusing on a single strategy, the Department should follow a combination of policies including pharmaceutical pricing regulations for ensuring availability and affordability of quality medicines, both generic and branded. (Para 35)

The Committee welcomes the proposal of setting up the Central Procurement Agency as an autonomous society as it can help control drug prices through procurement process. The Department may move the Cabinet for its approval with a sense of urgency. (Para 36)

Now that the Working Groups have already submitted their reports, the Committee recommends to the Department of Pharmaceuticals to finalise the New Pharmaceutical

Policy without further loss of time. The Committee desires to be kept apprised of the updated status in this regard. (Para 48)

The Committee would also like to be kept informed of the findings of the Task Force constituted by the Ministry of Health and Family Welfare and action taken thereon. (Para 49)

The Committee notes that as of now there is no mechanism in place to regulate the prices of new patented drugs which are imported in the country and sold at supernormal profits, whereas prices of the same medicines are considerably lower in other countries. The Committee does not accept the submission made by the Secretary (Pharmaceuticals) that there is no price control of a patented drug for open market. The Committee would like to observe that India as a sovereign country has every right to decide the prices of a drugs which are sold in the open market. The Committee therefore recommends to evolve an effective mechanism to control prices of imported patented drugs being sold in Indian Market. (Para 50)

The Committee also takes note of the submissions of the Secretary (Pharmaceuticals) to the effect that the issue of price regulation of imported molecules being sold in the country at high prices will be taken care of in the New Pharmaceutical Policy which is currently under finalization. The Committee feels that the issue at hand is too urgent to be left open-ended and, therefore, recommends that Department of Pharmaceuticals resolve this issue within a period of six months. The Committee would also like the Department to put in place an effective mechanism to enable the use of international price benchmarks in such cases and limit the price of an imported drug by comparison with the price of the same drug in other countries and thus check windfall profits made by importers on selling imported molecules at exorbitant prices in the country. (Para 51)

The Committee observes that serious anomalies exist in the law inasmuch as while there is a code of conduct for doctors forbidding them from accepting any gift, hospitality, trips to foreign and domestic destinations, no such legal provisions for penalizing pharma companies indulging in the unethical practices of bribing the doctors by way of offering expensive gifts, cash payments or sponsoring of pleasure trips, are in force. Keeping in view the fact that it is no secret that promotional costs are loaded into the price of prescription drugs and constitute a major part of the price of the drugs, the Committee welcomes the move towards framing a Uniform Code of Pharmaceutical Marketing Practices. However, the Committee is at a loss to understand as to why the Code has been made a voluntary code and not a statutory one. The Committee has been given to understand that the voluntary code has generally not been successful in curbing unethical practices and off-label promotion of drugs. The Committee notes that the Secretary (Pharmaceuticals) was not able to offer any valid reason for not making the Uniform Code a statutory provision. (Para 61)

The Committee therefore, recommends that the Department of Pharmaceuticals should take decisive action in making the Uniform Code mandatory so that effective check could be put on huge promotional costs and the resultant impact of the add-on costs on medicine prices. (Para 62)

The Committee observes that as of now the onus of checking unethical promotion of drugs by Pharma companies lies exclusively with the Department of Pharmaceuticals (which is primarily mandated to act as a catalyst for the growth of the pharma industry in the country) and the Ministry of Health and Family Welfare has no role to play in this matter, though protection of patients is the job of the latter. The Committee, therefore, fails to

understand, much less appreciate, the reasons behind the Department of Pharmaceuticals dealing with this issue exclusively, though Code of Conduct in pharmaceutical marketing affects both doctors and patients. Keeping this in view and also the fact that all over the world, such activities are under the National Drug Regulatory Authorities, the Committee, recommends that the Ministry of Health and Family Welfare may also be involved in implementation of Code of Conduct in Pharmaceutical Marketing. (Para 63)

After the presentation of the report, the only action taken by the Department of Health and Family Welfare was that it had requested the Department of Revenue to examine this issue of penalizing drug companies indulging in unethical promotion of drugs. The Committee is not aware of any further development in the matter. (Para 64)

The Committee, therefore, recommends that the Department of Health and Family Welfare actively pursue the matter with the Department of Revenue. (Para 65)

The Committee observes that almost a year has elapsed since the Committee presented its 45th Report to the Parliament but except the constitution of a Working Group to look into the matter of pricing of medicines no forward movement on putting a cap on the profit margin of medicines has been reported. (Para 73)

It has been a well-documented fact in India that high medicine prices are one of the biggest obstacles towards access to affordable treatment. Availability of the quality-assured affordable medicines is a vital prerequisite for affordable treatment. But given the financial profile of the general masses in the country, leaving the prices of medicines unregulated and entirely to the mercy of the market economy is unlikely to achieve the public health objectives. In such a scenario, expecting the free market system to ensure access to essential medicines is unrealistic. The Committee, therefore, reiterates its earlier recommendation of initiating the process of examining the issue of a blanket cap on profit margins of all medicines across the board. The Committee also recommends to expedite the matter. (Para 74)

The Committee had recommended preventing takeover of domestic companies by MNCs and thus preserving in-house manufacturing capability in the country. Precious time has been lost due to delay on part of the Government to act in this regard and many more Pharma companies have since been taken over since the recommendation was made by this Committee. Even though the Committee feels the ideal route for regulating Foreign Direct Investment (FDI) in brown-field Pharma projects would have been through the FIPB, the Government in its wisdom has decided to achieve this through subjecting all such transactions to the scrutiny of the Competition Commission of India (CCI) after making necessary provisions in the operating norms to accommodate such transactions. The Committee partly welcomes this move as it feels that such a step would help create some system of checks and balances and therefore address public health requirements in India. At the same time the Committee observes that since most of such Mergers and Acquisitions in Indian Pharma Sector are done through Special Purpose Vehicles (SPVs), appropriate mechanisms will need to be put in place to strengthen CCI and enable it to oversee the FDI in the Indian brown-field Pharma companies without any threshold limit to be effective. The Committee desires to be apprised of the changes made in rules and regulations governing CCI to facilitate oversight by the CCI and check collusion and unfettered acquisition of Indian pharma companies. (Para 83)

84. **The Committee feels that the country holds a strong position in producing generic drugs. Besides, the country has a strong distribution network not only in the country but also in other developing and underdeveloped countries. The Committee, therefore, strongly**

recommends that the Government should make all-out efforts to arrest the trend of acquisition of domestic pharma companies by the foreign multi-national companies. Besides, no stone should be left unturned towards developing and gearing up all the public sector pharma companies for production of cheaper quality generic drugs by giving them full functional autonomy and adequate financial support so that requirement of the country's public health sector may be met and the likely impact of the above acquisition of the domestic companies is neutralized. (Para 84)

The Committee, therefore, recommends with all the power at its command that the Ministry of Health and Family Welfare in consultation with the other Ministries/ Departments involved address this issue as a matter of top priority and revisit the FDI policy at the earliest. (Para 85)

The Committee while welcoming the move of conducting a study to assess the impact of takeovers on the domestic pharmaceutical industry recommends that keeping in view the urgency of the issue, the study may be completed at the earliest. (Para 86)

MINUTES

IX

NINTH MEETING

(2011-12)

The Committee met at 2.00 P.M. on Friday, the 18th February, 2011 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

RAJYA SABHA

1. Shrimati Brinda Karat — *In the Chair*
2. Shri Janardhan Dwivedi
3. Shri Balbir Punj
4. Dr. Vijaylaxmi Sadho

LOK SABHA

5. Shri Ashok Argal
6. Shrimati Sarika Devendra Singh Baghel
7. Dr. Sanjay Jaiswal
8. Dr. (Shrimati) Kruparani Killi
9. Shri N. Kristappa
10. Dr. Tarun Mandal
11. Dr. Jyoti Mirdha
12. Dr. Anup Kumar Saha
13. Shrimati Meena Singh

SECRETARIAT

Shrimati Vandana Garg, *Additional Secretary*

Shri R.B. Gupta, *Director*

Shrimati Arpana Mendiratta, *Joint Director*

Shri Dinesh Singh, *Assistant Director*

Shri Satis Mesra, *Committee Officer*

WITNESSES

I. * * *

II. Department of Health and Family Welfare

1. Shri L.C. Goyal, Secretary
2. Dr. Surinder Singh, Drugs Controller General of India (DCGI)

*** Relates to other matter.

III. Department of Pharmaceuticals

1. Shri Mukul Joshi, Secretary
2. Dr. S. M. Jharwal, Chairman (NPPA)
3. Shri Devendra Chaudhry, Joint Secretary

2. In the absence of the Chairman of the Committee, Shrimati Brinda Karat presided over the meeting. At the outset, the Chairperson welcomed the Members of the Committee and apprised them of the agenda of the meeting. * * *

3. * * *

4. * * *

5. The Committee then heard the Secretary, Department of Pharmaceuticals, the Additional Secretary, Department of Health and Family Welfare and the Drug Controller General of India on the various issues arising out of the Action Taken Note furnished by the Department of Health and Family Welfare on the Committee's 45th Report on "Issues relating to availability of generic, generic-branded and branded medicines, their formulation and therapeutic efficacy and effectiveness" .

6. The Committee observed that the Action Taken Note (ATN) furnished by the Department of Health and Family Welfare lacked totality as a number of issues arising from Committee's recommendations as contained in the 45th Report were yet to be taken to their logical conclusion and that no time-frame was indicated in the ATN for formulating an effective drug supply policy for the purpose of making available quality medicines at affordable prices. The Committee also expressed reservation on a number of issues remaining unanswered in the ATN.

7. The Additional Secretary, Department of Health and Family Welfare admitted that more action needed to be taken on the entire gamut of the issues concerning availability of quality medicines at reasonable prices. He *inter alia* informed the Committee that the Department was giving very high priority to this issue and was in the process of formulating a plan of action in consultation with States and that the Chief Secretaries of the States had been asked to give an action plan in this regard by the 15th March, 2011. He also informed the Committee that two sub-groups had been set up to suggest the right policy-mix on the issue and that the sub-groups were expected to submit their report by the 31st March, 2011. He also assured the Committee that a Task Force on National Drugs Security would be constituted within two weeks and that it would be asked to give its report within three months. The Members raised a number of queries, some of which were answered by the Additional Secretary. He assured to furnish replies to the queries which remained unanswered during the course of the meeting.

8. The Secretary, Department of Pharmaceuticals during the course of his deposition, *inter alia* shed light on the practical difficulties in the supply chain of Jan Aushadhi Scheme, review of the integrated business plan of Jan Aushadhi Scheme, target of 3000 sub-divisions of the country to be covered under Jan Aushadhi Scheme, subsidization of Jan Aushadhi Stores till they become financially viable. Some of the other issues of vital public importance which figured in the discussion with the Secretary, Department of Pharmaceuticals were artificially hiked prices of medicines because of monopoly, steps taken about reasonable pricing of drugs, revision of Drug Price Control Order (DPCO) and the time-frame for this exercise, revisitation of the issue of Foreign Direct Investment (FDI) in Pharma Sector, etc. The Members raised a number of queries, some of which were answered by the Secretary. He assured to furnish replies to the queries which remained unanswered during the course of the meeting.

*** Relate to other matters.

9. The Committee was not happy with the casual replies given by the Secretary, Department of Pharmaceuticals and felt that he did not address, in a satisfactory manner, the basic concerns raised by it during the course of the meeting and his approach was largely lackadaisical.

10. * * *

11. * * *

12. * * *

13. A verbatim record of the proceedings of the meeting was kept.

14. The Committee then adjourned at 4.26 P.M.

*** Relate to other matters.

XIII

THIRTEENTH MEETING

(2011-12)

The Committee met at 3.00 P.M. on Friday, the 3rd June, 2011 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

RAJYA SABHA

1. Shri Rasheed Masood — *In the Chair*
2. Shri Janardan Dwivedi
3. Shrimati Viplove Thakur
4. Dr. Prabhakar Kore
5. Shrimati Brinda Karat
6. Shrimati B. Jayashree

LOK SABHA

7. Shrimati Sarika Devendra Singh Baghel
8. Shri Vijay Bahuguna
9. Dr. Sanjay Jaiswal
10. Shri S.R. Jeyadurai
11. Dr. (Shrimati) Kruparani Killi
12. Shri N. Kristappa
13. Dr. Tarun Mandal
14. Shri Datta Meghe
15. Dr. Jyoti Mirdha
16. Shrimati Jayshreeben Patel
17. Shri R.K. Singh Patel
18. Dr. Anup Kumar Saha
19. Dr. Arvind Kumar Sharma
20. Shrimati Meena Singh
21. Shri Ratan Singh

SECRETARIAT

Shrimati Vandana Garg, *Additional Secretary*

Shri R.B. Gupta, *Director*

Shrimati Arpana Mendiratta, *Joint Director*

Shri Dinesh Singh, *Assistant Director*

WITNESSES

Department of Health and Family Welfare

1. Shri K. Chandramouli, Secretary
2. Dr. R.K. Srivastava, Director General of Health Services
3. Shri L.C. Goyal, Additional Secretary
4. Dr. Surender Singh, Drug Controller General of India
5. Dr. Sangeeta Sharma, Secretary, Medical Council of India (MCI)

Department of Pharmaceuticals

1. Shri Mukul Joshi, Secretary
2. Shri G. Balachandhran, Chairman (NPPA)
3. Dr. V. Rajagopalan, Additional Secretary & FA
4. Shri Devendra Chaudhry, Joint Secretary
5. Shri Arun Jha, Joint Secretary

2. In the absence of the Chairman of the Committee, Shri Rasheed Masood presided over the meeting. At the outset, the Chairperson welcomed Members of the Committee and apprised them of the agenda of the meeting.

3. * * *

4. Thereafter, the Committee heard views of the Secretary of Department of Health and Family Welfare along with the Drug Controller General of India (DCGI) and the Secretary of Department of Pharmaceuticals on the various issues arising out of the final Action Taken Note (ATN) furnished by the Department of Health and Family Welfare on the Committee's 45th Report on 'Issues relating to availability of generic, generic-branded and branded medicines, their formulation and therapeutic efficacy and effectiveness'.

5. The Secretary, Department of Health and Family Welfare during the course of his deposition, *inter alia* apprised the Committee of the steps being taken in the matter like promotion of generic medicines in the country; inclusion of 348 ingredient generic drugs in the National List of Essential Medicines, 2011 (NLEM); constitution of a Task Force for formulating a long-term policy and strategy for strengthening of the drug sector in the country; common generic formulary for all Government hospitals and CGHS wellness centres; introduction of UG Pharmacology curriculum by MCI about the essential drugs; controlling drug prices by setting up procurement and supply chain; putting in place a Central procurement policy to control the prices of drugs; taking up the issue of FDI policy in pharma sector with the Department of Industrial Policy and Promotion under the Ministry of Commerce and Industry; setting up of procurement and supply chain systems in the States; unethical practice of bribing doctors to promote drugs and the action taken by the Ministry in this regard and the ambit of the Ministry to punish the pharma companies which resort to such practices, by means of law in this regard; amendment of the Drugs and Cosmetics Act with respect to labelling requirements etc.

6. The Secretary, Department of Pharmaceuticals, during course of his deposition, highlighted the proposed expansion of Jan Aushadhi Scheme, constraints faced in the supply and distribution chains and the steps contemplated to overcome them; status of finalization of new Pharmaceutical Policy; price control over drugs; role of State Governments in implementation of Jan Aushadhi

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*** Relates to other matter.

Stores; reports of Working Groups set up to look into pricing and quality aspects of medicines; bulk drugs included in Drug Price Control Order; revival of Pharma PSUs *viz*. Hindustan Antibiotics, Bengal Chemicals and IDPL; steps contemplated to be taken to stop takeover of Indian Pharma Companies by MNCs, etc.

7. During the course of the meeting, Members raised a number of queries some of which were answered by the witnesses. The Committee was of the view that most of the questions were not answered properly. The Committee accordingly directed the Secretariat to forward the questionnaire to the witnesses for seeking written replies to these questions.

8. * * *

9. A verbatim record of the evidence tendered before the Committee was kept.

10. The Committee then adjourned at 4.35 P.M.

*** Relates to other matter.

XII

TWELFTH MEETING

(2011-12)

The Committee met at 10.30 A.M. on Friday, the 4th May, 2012 in Room No. 63, First Floor, Parliament House, New Delhi.

MEMBERS PRESENT

RAJYA SABHA

1. Shri Brajesh Pathak — *Chairman*
2. Dr. Prabhakar Kore
3. Shri Balbir Punj

LOK SABHA

4. Dr. Jyoti Mirdha
5. Shri M.K. Raghavan
6. Shri Ashok Argal
7. Shrimati Harsimrat Kaur Badal
8. Dr. Monazir Hassan
9. Shri P. Lingam
10. Shri J.M. Aaron Rashid
11. Dr. Arvind Kumar Sharma
12. Shri Ratan Singh

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*

Shri R.B. Gupta, *Director*

Shrimati Arpana Mendiratta, *Joint Director*

Shri Dinesh Singh, *Deputy Director*

2. At the outset, the Chairman welcomed the Members of the Committee and apprised them of the agenda of the meeting, *i.e.*, consideration and adoption of draft 58th Report on action taken by the Government on the Recommendations/Observations contained in the Forty Fifth Report of the Committee on Issues relating to availability of Generic, Generic-Branded and Branded Medicines, their Formulation and Therapeutic Efficacy And Effectiveness * * *. He invited Members to give their suggestions. The Committee then discussed the two draft Reports. A few changes were suggested by the Members for incorporation in the Reports and then the Committee adopted both the Reports with some modifications. The Committee, thereafter, decided that the Reports may be presented to the Rajya Sabha and laid on the Table of the Lok Sabha on Wednesday, the 8th May, 2012. The Committee authorized its Chairman and in his absence,

*** Relates to other matter.

Shri Balbir Punj and Dr. Prabhakar Kore to present the Reports in Rajya Sabha, and Dr. Jyoti Mirdha, and in her absence, Dr. Sanjay Jaiswal to lay the Reports on the Table of the Lok Sabha.

3. * * *

4. * * *

5. * * *

6. The Committee adjourned at 11.00 A.M.

*** Relate to other matters.

I

FIRST MEETING

(2011-12)

The Sub-Committee met at 11.30 A.M. on Tuesday, the 10th April, 2012 in Room No. 125 (Chairman's Room), First Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Dr. Jyoti Mirdha — *Convenor*

RAJYA SABHA

2. Shri Balbir Punj

LOK SABHA

3. Dr. Sanjay Jaiswal

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*

Shrimati Arpana Mendiratta, *Joint Director*

2. At the outset, the Convenor welcomed Members of the Sub-Committee to its first meeting and apprised them about the agenda of the meeting *i.e.* to consider the draft Reports on (i) the Action Taken Note (ATN) furnished by the Department of Health and Family Welfare on the Recommendations/Observations as contained in its 45th Report of the Committee on "Issues relating to availability of generic, generic-branded and branded medicines, their formulation and therapeutic efficacy and effectiveness"; and (ii) * * *.

3. The Sub-Committee then discussed both the draft Reports. The discussion remained inconclusive and the Sub-Committee decided to meet again on 11th April, 2012 for further consideration and adoption of the draft Reports.

4. The Sub-Committee adjourned at 12.30 P.M.

*** Relates to other matter.

II
SECOND MEETING
(2011-12)

The Sub-Committee met at 12.45 P.M. on Wednesday, the 11th April, 2012 in Main Committee Room, Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Dr. Jyoti Mirdha — *Convenor*

RAJYA SABHA

2. Shri Balbir Punj

LOK SABHA

3. Dr. Sanyay Jaiswal

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*

Shrimati Arpana Mendiratta, *Joint Director*

Shri Dinesh Singh, *Deputy Director*

2. At the outset, the Convenor welcomed Members of the Sub-Committee and apprised them about the agenda of the meeting *i.e.* to further consider the draft Reports on (i) the Action Taken Note (ATN) furnished by the Department of Health and Family Welfare on the Recommendations/ Observations as contained in its 45th Report of the Committee on "Issues relating to availability of generic, generic-branded and branded medicines, their formulation and therapeutic efficacy and effectiveness"; and (ii) * * *.

3. The Sub-Committee then discussed both the draft Reports. After discussion, the Sub-Committee adopted both the Reports with some modifications and decided to place the same before the Main Committee for consideration and adoption at a date to be decided by the Chairman of the Committee.

4. The Sub-Committee adjourned at 1.05 P.M.

*** Relates to other matter.

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